§ 5.601 Exemption of electronic products from performance standards and prohibited acts.

(a) The following officials are authorized to exempt from performance standards any electronic product intended for use by departments or agencies of the United States under section 534 (a)(5) of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 360kk(a)(5)) and to exempt an electronic product or class of products from all or part of the provisions of section 538(a) of the act (21 U.S.C. 360oo(a)) under section 538(b) of the act (21 U.S.C. 360oo(b)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Compliance, CDRH.

(b) These officials may not further redelegate this authority.

§ 5.602 Testing programs and methods of certification and identification for electronic products.

(a) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Compliance, CDRH, are authorized to review and evaluate industry testing programs under section 534(g) of the Federal Food, Drug and Cosmetic Act the act (21 U.S.C. 360kk(g)) and to approve or disapprove alternate methods of certification and identification and to disapprove testing programs upon which certification is based under section 534(h) of the act (21 U.S.C. 360kk(h)).

(b) These officials may not further redelegate this authority.

§ 5.603 Notification of defects in, and repair or replacement of, electronic products.

(a) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Compliance, CDRH, are authorized to perform all functions of the Commissioner of Food and Drugs (Commissioner), relating to notification of defects in, noncompliance of, and repair or replacement of or refund for, electronic products under section 534 of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 360kk) and under §§ 1003.11, 1003.22, 1003.31, 1004.2, 1004.3, 1004.4, and 1004.6 of this chapter; and Regional Food and Drug Directors, District Directors, and the Director, St. Louis Branch, are authorized to perform all such functions relating to:

(1) Assemblers of diagnostic x-ray systems, as defined in § 1020.30(b) of this chapter.

(2) Manufacturers of sunlamp products and ultraviolet lamps intended for use in any sunlamp product, as defined in § 1040.20(b) of this chapter.

(b) The Director and Deputy Director, Office of Compliance, CDRH, and the Division Directors, Office of Compliance, CDRH, are authorized to notify manufacturers of defects in, and noncompliance of, electronic products under section 535(e) of the act (21 U.S.C. 360ll(e)) and under § 1003.11(a) of this chapter; and the chiefs of District Compliance Branches are authorized to perform all such functions relating to:

(1) Assemblers of diagnostic x-ray systems, as defined in § 1020.30(b) of this chapter.

(2) Manufacturers of sunlamp products and ultraviolet lamps intended for use in any sunlamp products, as defined in § 1040.20(b) of this chapter.

(c) These officials may not further redelegate these authorities.

§ 5.604 Manufacturers requirement to provide data to ultimate purchasers of electronic products.

(a) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health, are authorized to require manufacturers to provide performance and technical data to the ultimate purchaser of electronic products under section 537(c) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360nn(c)).

(b) These officials may not further redelegate these authorities.